UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE CHECKPOINT THERAPEUTICS, INC. SECURITIES LITIGATION	Case No. 1:24-cv-02613-PAE **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

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EXHIBIT LIST

Lead Plaintiff Hamilton Bailey and named plaintiff Reiko Juhst ("Plaintiffs"), individually and on behalf of all others similarly situated, by and through their attorneys, allege the following based upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes, without limitation: (a) review and analysis of regulatory filings made by Checkpoint Therapeutics, Inc. ("Checkpoint" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued and disseminated by Checkpoint; (c) review and analysis of documents from the U.S. Food and Drug Administration ("FDA"); (d) consultation and interviews with industry experts; and (e) review of other publicly available information concerning Checkpoint.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of a class consisting of all persons and entities who purchased the publicly traded common stock of Checkpoint, and/or purchased publicly traded call options on such stock, and/or wrote publicly traded put options on such stock (all such stock and options are collectively referred to herein as "Checkpoint Securities") between March 10, 2021 and December 15, 2023, both dates inclusive (the "Class Period"), and who were damaged thereby. Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. Checkpoint is a small company attempting to develop and gain FDA approval to market drugs for the treatment of certain cancers. During the Class Period Checkpoint had no FDA-approved products, negligible revenue, and limited cash on hand, and was dependent on

raising funds from investors in order to continue its operations. Checkpoint sold at least $79 million of artificially inflated securities during the Class Period.

3. At all relevant times Checkpoint's lead product candidate has been cosibelimab, which the Company describes as an anti-programmed death-ligand 1 ("PD-L1") antibody, intended to treat locally advanced and metastatic cutaneous squamous cell carcinoma ("CSCC"), a form of skin cancer. Checkpoint's business prospects depended in large part on near-term regulatory approval of cosibelimab, which was highly important to Checkpoint's investors.

4. In 2017 Checkpoint hired Samsung Biologics as its contract manufacturing organization ("CMO"). Because Checkpoint was a small company with limited resources, it could not manufacture the biologic substances for its product candidates in-house, and so outsourced that function to Samsung Biologics. In October 2020 Checkpoint executed a product-specific agreement for Samsung Biologics to manufacture cosibelimab.

5. Due to the high importance of product quality in ensuring that drugs are safe to use, the FDA requires inspections of manufacturing facilities to assess compliance with the FDA's current Good Manufacturing Practices ("cGMP"), regulations that contain minimum requirements for manufacturers concerning all aspects of production. FDA inspectors document any conditions that in their judgment may constitute violations of laws and regulations enforced by the FDA, including cGMP, on FDA Form 483 Inspection Observations, and the FDA provides a copy to the manufacturer. A key requirement of cGMP and focus of FDA inspections is data integrity—manufacturers must ensure their data is accurate and reliable. Inspection observations of significant or recurring cGMP violations can, and often do, result in the FDA rejecting applications for approval to market new drugs. As such, strict adherence to cGMP, including data integrity

requirements, is extremely important for CMOs like Samsung Biologics, drug development companies like Checkpoint, and their investors.

6. Checkpoint's contracts required Samsung Biologics to provide Checkpoint with substantial information about the CMO's quality operations, cGMP compliance, and interactions with the FDA, and provided numerous means for Checkpoint and Samsung Biologics to closely collaborate on quality and regulatory issues. This is in line with both Samsung Biologics' general practices and industry standard practices, under which drug owners and CMOs routinely share detailed information about quality issues and communications with the FDA.

7. Despite having substantial information about Samsung Biologics' quality issues and interactions with the FDA, throughout the Class Period Defendants concealed from investors adverse information about repeated FDA observations of cGMP violations by Samsung Biologics. Defendants failed to disclose that leading up to and during the Class Period the FDA repeatedly issued Form 483s to Samsung Biologics noting multiple violations including significant data integrity problems. From 2016 through February 2023, the FDA inspected Samsung Biologics 10 times and issued 10 Form 483s, containing numerous observations of problematic conditions. All the while, Defendants touted their relationship with Samsung Biologics, and misleadingly stated that Checkpoint's business could be adversely affected *if* its CMO failed to comply with cGMP.

8. On January 3, 2023, Checkpoint announced that it had submitted a Biologics License Application ("BLA") to the FDA for the approval of cosibelimab. A BLA is a request for permission to market a biologic product, and must include voluminous information about the applicant, product, its intended use and labelling, the manufacturing process, and supporting clinical studies. The FDA reviews BLAs using a standardized process and timeline, which includes evaluation, and in many cases pre-approval inspection, of all manufacturing facilities for the

product. Submission of a BLA is a major milestone for a company like Checkpoint and its investors, because if approved by the FDA it allows the company to market its product and potentially earn substantial revenues. Under the FDA's one-year review timeline, a decision on Checkpoint's BLA for cosibelimab was expected on or around January 3, 2024.

9. Throughout the FDA's review of the cosibelimab BLA, Defendants selectively disclosed only positive interactions with the FDA, creating a materially misleading impression of its chances for approval. Over August 21-September 1, 2023, the FDA conducted an inspection of Samsung Biologics relating to Checkpoint's BLA for cosibelimab, and certain other products including Eli Lilly and Company's ("Eli Lilly") lebrikizumab which was then also the subject of a pending BLA. At the conclusion of the inspection the FDA issued a Form 483 to Samsung Biologics with multiple observations, first and foremost including critical problems with respect to data integrity, stating in part that "there is no means of determining with absolute certainty the true reliability of all test data" used in support of application submissions. Reporting by South Korean media has revealed additional details about Samsung Biologics' data integrity problems, including that executives deliberately falsified data and were fired after an internal investigation.

10. Data integrity issues have been a key focus for the FDA in recent years, and the observations noted on the Form 483 created material risks to the approval of the cosibelimab BLA. Indeed, the FDA rejected Eli Lilly's BLA for lebrikizumab on or about October 2, 2023, due to the same issues noted in the September 1, 2023 Form 483 to Samsung Biologics. However, after the Form 483 was issued, Defendants failed to disclose these problems and continued to misleadingly tout only positive interactions with the FDA in their public statements. It was not until November 13, 2023 that Defendants publicly acknowledged the existence of a Form 483,

while concealing its troubling contents and misleadingly stating that they believed the issues would be successfully resolved before the FDA completed its review of the cosibelimab BLA.

11. On December 18, 2023, Checkpoint disclosed that the FDA had issued a Complete Response Letter ("CRL") in response to the cosibelimab BLA, rejecting the application due to findings from the FDA's inspection of Checkpoint's CMO, Samsung Biologics. This news shocked investors, from whom Defendants had concealed the material risks to the BLA's approval arising from Samsung Biologics' repeated cGMP violations and data integrity problems. Checkpoint's stock price promptly crashed by 44.9% on exceptionally high trading volume.

12. As a result of Defendants' misleading statements and omissions, and the resulting precipitous decline in the market value of Checkpoint's common stock, Plaintiffs and other Class members have suffered significant losses and damages.

II. JURISDICTION AND VENUE

13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). The alleged misstatements entered and subsequent damages took place within this judicial district. Checkpoint's common stock trades on the NASDAQ Capital Market ("NASDAQ"), which is headquartered in this Judicial District. At the beginning of the Class Period, Checkpoint's SEC filings listed its principal executive office address as 2 Gansevoort Street, 9th Floor, New York, New York 10014. Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District.

16. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

17. Lead Plaintiff Hamilton Bailey, as set forth in his previously filed certification (Dkt. No. 19-2), incorporated by reference herein, purchased Checkpoint Securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

18. Plaintiff Reiko Juhst, as set forth in the attached certification (**Exhibit 1**), purchased Checkpoint Securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

19. Defendant Checkpoint Therapeutics, Inc. is incorporated in Delaware and currently maintains its principal executive offices at 95 Sawyer Road, Suite 110, Waltham, Massachusetts 02453. Checkpoint's common stock is listed and trades on the NASDAQ under the ticker symbol "CKPT".

20. Defendant James F. Oliviero has been Checkpoint's CEO and President since October 2015, and a member of its Board of Directors since October 2018. He has nearly 25 years of experience in the biotechnology industry, including in executive roles in which he oversaw matters including clinical study design, regulatory oversight, investor relations, and legal functions. He has an undergraduate degree in finance and is a CFA charterholder, and began his career as an investment banker.

21. Defendant Oliviero, because of his positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Defendant Oliviero was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his positions and access to material non-public information available to him, Defendant Oliviero knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations that Defendants made were then materially false and/or misleading. Defendant Oliviero is liable for the false statements pleaded herein.

22. The Company and Defendant Oliviero are referred to herein, collectively, as the "Defendants."

IV. BACKGROUND

A. Checkpoint Was A Small Company Whose Prospects Substantially Depended On Near-Term FDA Approval Of Cosibelimab

23. At all times during the Class Period, Checkpoint was a small company with few employees, no products approved for sale by the FDA (or any other regulator), and no product sales.

24. At year-end 2020 Checkpoint had 10 full or part-time employees, increasing to 14 at year-end 2021, and 24 at year-end 2022, before decreasing to 23 at year-end 2023.

25. Checkpoint reported the following balance sheet information (in thousands of dollars):

	12/31/2023	12/31/2022	12/31/2021	12/31/2020
Cash and cash equivalents	4,928	12,068	54,735	40,772
Total Assets	5,378	13,290	55,728	42,596
Total Liabilities	18,425	32,773	25,982	7,217

26. Checkpoint reported the following on its statements of operations (in thousands of dollars):

	2023	2022	2021	2020
Revenue (all from related party)	103	192	268	1,069
Operating expenses	52,251	58,525	56,991	24,270
Net loss	51,847	62,624	56,670	23,081

None of Checkpoint's revenue came from product sales. All of the revenue it reported in this period came from related party TG Therapeutics, Inc. pursuant to a collaboration agreement and a sublicense agreement.

27. Because Checkpoint had limited and dwindling cash, no sales, little revenue, and substantial expenses, it had to continuously raise money from investors in order to survive. From August 12, 2022, when Checkpoint filed its Form 10-Q for the second quarter of 2022, through the end of the Class Period, each of the Company's annual and quarterly reports disclosed that "[a]s a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given."

28. At all times during the Class Period, Checkpoint's lead product candidate (*i.e.*, closest to a potential regulatory approval) was cosibelimab. Checkpoint describes cosibelimab as an anti-programmed death-ligand 1 ("PD-L1") antibody, which Checkpoint intends to market to treat locally advanced and metastatic cutaneous squamous cell carcinoma ("CSCC"), a form of skin cancer.

29. Through the end of the Class Period, Checkpoint did not submit any applications for regulatory approval to market products other than cosibelimab. Checkpoint's second most advanced product under development was olafertinib, which as of the end of the Class Period remained in an ongoing Phase 3 study being conducted by a partner company. A Phase 3 study is meant to establish the drug's safety and efficacy in a wider patient population than initial studies, and is required for potential regulatory approvals to market the product. By the end of the Class Period, no other Checkpoint products had even advanced to Phase 3 studies.

30. Therefore, even if the substantial costs and risks to regulatory approval could be overcome, any potential regulatory approvals for Checkpoint's drugs under development other than cosibelimab were still years away. Given Checkpoint's limited cash, minimal revenues, and substantial operating expenses, Checkpoint's ability to survive long enough to succeed as a company at all times depended in substantial part on achieving near-term regulatory approval for its lead product candidate, cosibelimab.

B. Checkpoint Hired Samsung Biologics To Manufacture Cosibelimab, And Monitored Its Quality And Regulatory Compliance

31. Checkpoint and Samsung Biologics entered into a Master Services Agreement that became effective on November 8, 2017 (the "MSA"), under which Checkpoint agreed to pay Samsung Biologics for certain biologics manufacturing services, with the products, manufacturing services, and payments to be further detailed in future Product Specific Agreements ("PSAs"). *See* **Exhibit 2**. The MSA was signed on behalf of Checkpoint by Defendant Oliviero.

32. The MSA, through numerous provisions, gave Checkpoint the ability to oversee Samsung Biologics' quality with respect to Checkpoint products, and to be involved in any regulatory inspections concerning Checkpoint products. For example:

a. Sections 2.3, 8.1 and 1.60 provide that Checkpoint and Samsung Biologics will finalize and adhere to a Quality Agreement with respect to each PSA that "governs their respective responsibilities related to quality systems and quality requirements";

b. Sections 3.2 and 1.44 provide that for each product to be manufactured, Checkpoint and Samsung Biologics will create a "Joint Steering Committee" of their personnel, which shall, among other things, monitor "strategies for the Regulatory Approval of the Facility to Manufacture the Product," "ensure that the Manufacturing Process" including applicable Quality Agreement provisions "is being implemented appropriately," and resolve quality, regulatory, or other issues that cannot be resolved by the Core Team;

c. Section 3.3 provides that for each product to be manufactured, Checkpoint and Samsung Biologics will create a "Core Team" of their personnel, which shall, among other things, "report periodically on operation and quality progress and performance," "investigate and resolve . . . quality, regulatory or other issues arising during the Service," "review and escalate to the [Joint Steering Committee], as needed, changes to the . . . applicable [Quality Agreement]," and coordinate activities relating to quality aspects of manufacturing;

d. Sections 4.2 and 1.25 provide that Samsung Biologics shall maintain its facilities in compliance with current Good Manufacturing Practices, including FDA requirements;

e. Section 4.6 provides that Samsung Biologics shall provide Checkpoint personnel access to its facilities to coordinate and guide Samsung Biologics' services;

f. Sections 6.2 and 1.66 provide that Samsung Biologics will provide Checkpoint with notice of any changes required by the FDA or other regulators, implement such changes, provide Checkpoint with regular updates on the progress of implementation, and provide Checkpoint with written notice if it becomes aware of any cause which may delay implementation.

g. Section 7.1 provides that Samsung Biologics shall provide reasonable assistance and cooperation in order for Checkpoint to obtain regulatory approvals;

h. Sections 7.3 and 1.66 provide that Samsung Biologics shall facilitate on-stie inspections conducted by the FDA or other regulators, and notify Checkpoint of any contacts or inquiries by the FDA or other regulators including "inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result" related to Samsung Biologics' manufacture of Checkpoint products;

i. Sections 7.3 and 1.66 further provide Checkpoint the right to witness any FDA inspection related to the manufacture of its products, and to attend any wrap-up meeting between Samsung Biologics and the FDA relating to such an inspection;

j. Sections 7.3 and 1.66 also provide that Samsung Biologics "shall timely provide [Checkpoint] with a copy of any Form 483, inspection report or regulatory letter issued by [the FDA] and shall provide [Checkpoint] a meaningful opportunity to review and comment upon any response of [Samsung Biologics] thereto"; and

k. Section 8.3.1 provides that Checkpoint may audit Samsung Biologics' facilities upon request to ascertain its compliance with the terms of the MSA or a PSA.

33. On October 2, 2020, Checkpoint and Samsung Biologics entered into a PSA for the manufacture of cosibelimab, pursuant to the MSA. Neither the cosibelimab PSA, nor its Quality

Agreement, have been made publicly available. Checkpoint announced the cosibelimab PSA in a SEC Form 8-K filed on October 7, 2020, that was signed by Defendant Oliviero.

34. After the end of the Class Period, when discussing communications between the FDA and Samsung Biologics relating to the manufacture of cosibelimab, Defendant Oliviero stated that Samsung Biologics "share everything with us." *See infra* Part IX.

35. Manufacturing costs, primarily those for Checkpoint's lead product candidate cosibelimab, comprised a substantial portion of the Company's total expenses during the Class Period. Checkpoint's financial statements reported the following amounts (in thousands of dollars):

	2023	**2022**	**2021**	**2020**
Product manufacturing costs	19,000	25,300	17,000	1,700
Total operating expenses	52,251	58,525	56,991	24,270

Checkpoint has not reported using any contract manufacturers other than Samsung Biologics, and does not manufacture its own products. Checkpoint has not reported any PSAs pursuant to the MSA with Samsung Biologics other than the PSA for cosibelimab.

36. Despite being a small organization of only 10-24 employees during the Class Period, Checkpoint had several employees dedicated to quality, regulatory affairs, and CMO oversight. For example, according to their publicly available LinkedIn profiles:

a. Todd Banas, Vice President Biologics Technical Operations, has worked at Checkpoint since May 2023, and lists his top skills as including "Regulatory Compliance" and "CMO management," and further highlights his experience as a "Group and Program Leader with 25+ years of CMC experience in" matters including "technical manufacturing support and CMO oversight." His prior roles include Senior Director Contract Manufacturing at CinCor Pharma, Inc. from November 2022 to May 2023 and Senior

Director, Contract Manufacturing at Allena Pharmaceuticals, Inc. from September 2018 to June 2020.

b. Ed Chan, Director of Quality Assurance, has worked at Checkpoint since January 2022, describes himself as a "Pharmaceutical Quality Leader," includes "CMO" in his byline, lists skills including "Good Manufacturing Practice (GMP)" and "U.S. Food and Drug Administration (FDA)," and highlights his knowledge of "quality systems." Chan lists education including a "Biotechnology and Biomanufacturing Certificate." His prior roles include Associate Director, Technical Services, External Manufacturing at Amneal Pharmaceuticals from April 2015 to February 2020, where he "Led, tracked and managed Technical Transfer activities at Contract Manufacturing and Packaging Organizations" and "Collaborated with CMOs on manufacturing process development." He was also previously Associate Director, Quality, External Manufacturing at Impax Laboratories from December 2013 to March 2015. The FDA's establishment inspection report ("EIR") summary for its June 12-16, 2023 inspection of Checkpoint's headquarters lists Mr. Chan's duties as including "QA review/approval of reports, batch records, deviations, CMO change controls (day-to-day quality)."

c. Gerry Crudden, Sr. Director Operations and Supply Chain, has worked at Checkpoint since September 2021, and lists his responsibilities at the Company as including "Maintain compliance of all GMP regulations for supply operations," "Provide financial and operational oversight of CMO/3PL partners," and "Lead and manage relationships with labeling/packaging/distribution Contract Manufacturing Organizations to provide operational oversight and evaluation to improve and enhance the supply chain."

d. Fenella Keig, Quality Systems Director, has worked at Checkpoint since January 2022, and describes herself as a "GMP Compliance specialist."

e. Meredith McConnell, Senior Quality Assurance Manager, has worked at Checkpoint since December 2020, and lists her responsibilities at the Company as including "Responsible for overseeing GMP testing at CMO/external testing sites for in-process, drug substance, and drug product," "Verify and review analytical source data to ensure data integrity, traceability, and compliance," "Responsible for developing and maintain relationships with CMO/external laboratories," "Responsible for CMO/external laboratory oversite [*sic*] to ensure compliance," "Responsible for coordinating and conducting supplier audits," "Author and approve regulatory submissions related to QC, such as IND/BLA. Provide responses to regulatory agency (FDA, EMA, PMDA, etc.) questions related to QC," and "Compile and review CMO executed batch records."

f. Daniel Peng, Senior Director, Regulatory Affairs CMC, has worked at Checkpoint since March 2022, and highlights his experience including "6 years in the US FDA for scientific and regulatory review of CMC sections across various types of regulatory submissions" including BLAs, and "7 years in leading global pharmaceutical companies (Shire and AstraZeneca) for product development and commercial manufacturing." In his prior role as a Quality Assessment Lead in the FDA/CDER/OPQ/Office of Process and Facilities he was "Responsible for primary and secondary scientific review of the manufacturing process and sites for NDAs, ANDAs, and certain complex INDs and meeting packages."

g. John Salvagno, Sr. Vice President Quality Operations, has worked at Checkpoint since November 2021, highlights his experience in "quality system

implementation," and describes himself as an "Experienced Regulatory Agency lead with FDA . . . with strong experience in positive GMP site system improvement and remediation." In his prior role as Principal of Dolomite Compliance Services LLC his responsibilities included "Site GMP Inspection Management FDA" and "Contract manufacturing compliance and quality management," and his specialties included "Managing Regulatory Authority Inspections and Follow Up Activities." The FDA's EIR summary for its June 12-16, 2023 inspection of Checkpoint's headquarters lists Mr. Salvagno's duties as including "[o]versight of all quality operations."

h. Scarlett Tumulty, Senior Director, Quality Compliance, has worked at Checkpoint since April 2022, describes herself as a "professional with over 20 years of experience in the pharmaceutical industry consistently assuming progressively greater management responsibilities in the areas of Quality, [and] Regulatory Affairs." Her "Quality experience includes oversight of all areas of Quality, including change control, investigations/deviations/CAPA, GMP training, complaint handling, vendor management/auditing, quality operations, and quality control." She describes herself as an "Experienced regulatory agency inspection lead with FDA" and highlights her "Strong site GMP system improvement and remediation experience, including leading FDA/DEA inspection teams."

37. The FDA's EIR summary for its June 12-16, 2023 inspection of Checkpoint's headquarters states that "[w]e determined that Checkpoint has established quality systems for vendor audits, data verifications, and process review to determine compliance with regulations."

C. The FDA's Current Good Manufacturing Practice Requirements, Including Data Integrity, And The Biologics License Application Process

38. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its current Good Manufacturing Practice regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

39. The approval process for new and generic drug marketing applications includes the FDA's review of the manufacturer's compliance with cGMP. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

40. Among the FDA's regulations relating to cGMP are 21 C.F.R. Part 314 concerning FDA approval to market a new drug, 21 C.F.R. Part 210 concerning cGMP in manufacturing of drugs, 21 C.F.R. Part 211 concerning cGMP for finished pharmaceuticals, and 21 C.F.R. Part 600 concerning biological products. Under the Food, Drug, and Cosmetic Act, drugs not manufactured in compliance with cGMP are considered "adulterated," and may not be introduced or delivered into interstate commerce. *See* 21 U.S.C. § 351(a)(2)(B); 21 U.S.C. § 331(a).

41. FDA guidance for industry titled "Contract Manufacturing Arrangements for Drugs: Quality Agreements" and dated November 2016 provides that both drug owners and their contract manufacturers are responsible for ensuring compliance with cGMP. The guidance states that "[w]hen an owner uses a contract facility, the owner's quality unit is legally responsible for approving or rejecting drug products manufactured by the contract facility, including for final release," and that "[t]he contract facility is also required to comply with statutory CGMP and applicable CGMP regulations, including requirements for its quality unit."

42. Data integrity is an important part of cGMP, and has been a key focus for the FDA in recent years. Data integrity refers to the completeness, consistency, and accuracy of data. FDA guidance requires data to be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (which the FDA refers to by the acronym "ALCOA").

43. Among the FDA's regulations relating to data integrity are: 21 C.F.R. § 211.68 (requiring that "backup data are exact and complete" and "secure from alteration, inadvertent erasures, or loss" and that "output from the computer . . . be checked for accuracy"); 21 C.F.R. §§ 211.100 and 211.160 (requiring that certain activities be "documented at the time of performance" and that laboratory controls be "scientifically sound"); 21 C.F.R. § 211.180 (requiring that records be retained as "original records," or "true copies," or other "accurate reproductions of the original records"); 21 C.F.R. §§ 211.188 and 211.194 (requiring "complete information," "complete data derived from all tests," and "complete record of all data,"); 21 C.F.R. §§ 211.22, 211.192, and 211.194(a) (requiring that production and control records be "reviewed" and that laboratory records be "reviewed for accuracy, completeness, and compliance with established standards"); and 21 C.F.R. §§ 211.182, 211.186(a), 211.188(b)(11), and 211.194(a)(8) (requiring that records be "checked," "verified," or "reviewed").

44. FDA guidance for industry titled "Data Integrity and Compliance With Drug CGMP: Questions and Answers" and dated December 2018 provides that:

> In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ensuring data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees.

The guidance further provides that "[w]hile not in the scope of this guidance, data integrity-related CGMP violations can also impact or be directly linked to application filing, review, and regulatory

actions." According to the guidance, "[d]ata integrity is critical throughout the CGMP data life cycle, including in the creation, modification, processing, maintenance, archival, retrieval, transmission, and disposition of data."

45. The FDA's data integrity guidance states that companies "must exercise appropriate controls to assure that changes to computerized MPCRs [master production and control records] or other CGMP records or input of laboratory data into computerized records can be made only by authorized personnel", citing 21 C.F.R. § 211.68(b). The guidance further states that "[w]hen login credentials are shared, a unique individual cannot be identified through the login and the system would not conform to the CGMP requirements in parts 211 and 212," in part because actions with respect to cGMP data must be "attributable to a specific individual," citing 21 C.F.R. §§ 211.68(b), 211.188(b)(11), 211.194(a)(7) and (8), and 212.50(c)(10)). Further, "FDA expects processes to be designed so that data required to be created and maintained cannot be modified without a record of the modification," and so "it is not acceptable to store electronic records in a manner that allows for manipulation without creating a permanent record."

46. An April 26, 2022 presentation by FDA Senior Pharmaceutical Quality Assessor Shujun Chen, titled "Culture of Quality: Data Integrity and CGMP Compliance" states that a "[d]ata integrity breach is a violation of CGMP," that the FDA has "[i]ncreasingly observed CGMP violations involving data integrity during inspections," and the FDA has a "continued focus on data management and data integrity, particularly for electronic data." The presentation cites issues highlighted in recent FDA warning letters relating to data integrity, such as "Lack of controlled access to computer systems," "[d]eleted data, fabricating data," and inadequate remedial actions to fix data integrity problems. The presentation further states that "evaluation of data integrity is a

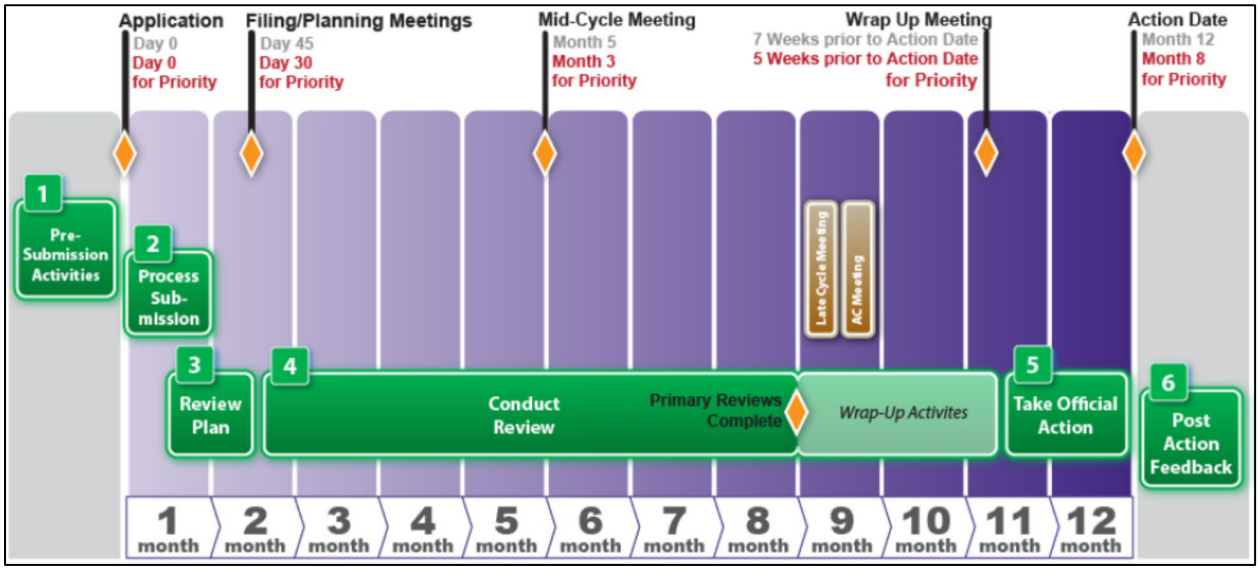
crucial aspect of OPMA's [Office of Pharmaceutical Manufacturing Assessment] application review."

47. Another April 26, 2022 presentation from the same conference, by Byeongtaek Oh form the FDA's OPMA, titled "Role of Data Integrity in Drug Applications" states that "[d]ata provided in drug applications must be reliable and trustworthy," and that "[f]ailure to uphold data integrity could cast doubt on all information submitted in the application." The presentation cites indicators of data integrity violations including "[f]ailure to prevent unauthorized access or changes to data" and "[f]ailure to have controls over electronic data." The presentation highlighted an instance where a "manufacturing facility lacked the necessary controls to assure the data in support of pending applications," and so the "[a]pplications received complete response (CR) actions due to the inability to establish the reliability of submitted data."

48. In order to obtain FDA approval to introduce a biologic product into interstate commerce, its sponsor must submit a Biologics License Application to the FDA. A BLA is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the clinical effects of a biological product. If the information provided meets FDA requirements, the application is approved, and a license is issued allowing the firm to market the product. The FDA reviews BLAs using a standardized process and timeline, which includes evaluation of all manufacturing facilities for the biologics product.

49. Once a BLA is accepted by the FDA for review, the FDA assigns a goal date to make a decision to approve or reject the BLA, approximately 12 months from submission, in accord with the requirements of the Prescription Drug User Fee Act of 1992 ("PDUFA"), as amended and reauthorized from time to time, including by the FDA User Fee Reauthorization Act

of 2022. The FDA's BLA review process generally proceeds according to the below depicted timeline, published by the FDA:



50. Throughout the BLA review process the FDA communicates with the sponsor about the status of the application and outstanding issues, including in connection with planned meetings such as the mid-cycle meeting (approximately five months after filing) and the late-cycle meeting (approximately nine months after filing).

51. According to a presentation by Sean Marcsisin form the FDA's Office of Pharmaceutical Quality Operations, titled "The Dos and Don'ts of Pre-Approval Inspections: What to Expect When Being Inspected" during the FDA's review of a BLA, all manufacturing sites for the product are evaluated, and a pre-approval inspection of one or more manufacturing sites may be scheduled if appropriate. According to the presentation "[t]he FDA performs pre-approval inspections to ensure that a manufacturing establishment named in a drug application is capable of manufacturing a drug, and that submitted data are accurate and complete." At the conclusion of the pre-approval inspection, the investigator will issue a Form 483 if significant cGMP violations are found, and will either recommend approval if the inspection found no significant issues, or

recommend withholding of approval if "the site is not cGMP compliant . . . or information submitted is not accurate and complete." The presentation lists reasons for "withhold" recommendations including "[s]ignificant data integrity problems."

52. FDA guidance concerning pre-approval inspections (compliance program manual 7346.832) lists four objectives for such inspections: (1) Objective 1: Readiness for Commercial Manufacturing; (2) Objective 2: Conformance to Application; (3) Objective 3: Data Integrity Audit; and (4) Objective 4: Commitment to Quality in Pharmaceutical Development. As part of the pre-approval inspection data integrity audit, the FDA will "[a]udit the accuracy and completeness of data reported by the facility for the product," in order to, "among other things, help to authenticate the data submitted in the CMC section of the application as relevant, accurate, complete, and reliable." As such, data integrity is a significant focus and concern for the FDA's pre-approval inspections.

D. BLA Sponsors And Contract Manufacturers, Including Samsung Biologics, Coordinate Closely On Quality Issues And FDA Inspections

53. As set forth in the declaration of Plaintiffs' expert consultant Jennifer Ahearn (**Exhibit 3**), it is industry standard practice for BLA sponsors (like Checkpoint) and their CMOs (like Samsung Biologics) to collaborate closely on quality issues throughout their relationship, in particular with respect to FDA pre-approval inspections, and there is typically frequent and detailed communication between sponsors and CMOs concerning quality issues that could affect the sponsor's product. *See* Ahearn Decl. ¶¶5, 17.

54. At the outset of the relationship, the sponsor typically evaluates potential CMOs on subjects including their quality systems and cGMP compliance, and the results of their prior regulatory inspections. *See id.* ¶¶6-7. This evaluation generally includes both a supplier questionnaire and an on-site audit of the CMO's facilities. *See id.*

55. After a sponsor selects and contracts with a CMO, the sponsor generally performs ongoing monitoring and oversight of the CMO and its cGMP compliance through multiple mechanisms. *See id.* ¶¶9-11. These include additional on-site audits, review of various quality metrics reported by the CMO to the sponsor on an ongoing basis, and standing meetings between teams of sponsor and CMO employees. *See id.*

56. When a sponsor submits a BLA to the FDA, there is typically additional close collaboration between the sponsor and its CMO, with the CMO providing critical manufacturing data and validation reports to support the submission, and providing regular updates to the sponsor concerning manufacturing progress and any problems arising. *See id.* ¶12.

57. Pre-approval inspection of a CMO by the FDA in connection with a BLA are scheduled in advance, with the CMO notifying the sponsor, allowing the sponsor and CMO to collaborate on preparing for the inspection. *See id.* ¶¶13-14. The sponsor will usually have its regulatory and quality personnel present at the CMO during the inspection, or at least available, to address FDA questions about the product. *See id.* ¶14. CMOs provide daily inspection summaries to the sponsor throughout the inspection, addressing potential deficiencies discussed with the FDA. *See id.* ¶15. At the conclusion of the inspection, the CMO provides any Form 483 issued by the FDA to the sponsor, and collaborates with the sponsor on a response to the FDA. *See id.*

58. Plaintiffs' counsel's interview with former Samsung Biologics employee Ronald Marchesani confirms that Samsung Biologics followed such industry standard practices, closely collaborating with its clients on quality issues and FDA inspections.

59. Ronald Marchesani worked for Samsung Biologics, at its headquarters in Incheon, South Korea, as Senior Vice President of the Quality Assurance Center from January 2015 through January 2018. In that role he oversaw Quality Assurance, Regulatory, CMC, and Quality Control.

He reported directly to the CEO of Samsung Biologics, and he oversaw a department of up to 700 employees.

60. According to Marchesani, before a prospective client selected Samsung Biologics as its contract manufacturer and entered into a master services agreement, typically the client would conduct a one to two week on-site visit at Samsung Biologics' facilities in Incheon (either through in house staff or external consultants) and would perform due diligence audits.

61. In Marchesani's experience, clients conducted ongoing monitoring of quality throughout their relationships with Samsung Biologics. A client would typically conduct a quality audit of Samsung Biologics every one or two years, depending on the terms of their quality agreement. Some clients had personnel on site at Samsung Biologics to conduct additional quality oversight during manufacturing of their products. Quality related issues were also discussed at regular meetings between clients' employees and their Samsung Biologics counterparts.

62. Marchesani recalled that Samsung Biologics regularly communicated with clients about quality issues affecting their products. If Samsung Biologics detected any process deviations it would promptly inform affected clients. Likewise, Samsung Biologics would inform clients of relevant quality observations from regulators. Samsung Biologics would inform clients about quality issues specifically relating to their products, and about more generally applicable significant quality issues that had the potential to affect the client's products.

63. Marchesani was responsible for overseeing and coordinating Samsung Biologics' preparation for and conduct during an FDA inspection that took place during October 12-20, 2015. This was a pre-approval inspection relating to BLAs then under review by the FDA, submitted by two different clients. Samsung Biologics closely communicated and coordinated with both clients

about the inspection. Marchesani recalled that the pre-approval inspection process was very demanding.

64. According to Marchesani, the FDA informed Samsung Biologics and these two clients about 3-4 months in advance that an inspection would take place, and approximately 2 months before the inspection informed them of the inspection's date and the identities of the inspectors. To prepare, prior to the inspection Samsung Biologics frequently communicated with its clients via phone calls and video meetings, and reviewed manufacturing batch records and other relevant documents with them.

65. Prior to and during the 2015 inspection, Samsung maintained separate communications with the two clients involved and did not reveal their identities to each other. However, both clients were informed that another client was involved in the inspection, and Marchesani believes it is possible that they were aware of each other's identities, for example through monitoring BLA news and data used by industry participants, professional connections among their personnel, or other means (both client teams, as well as the FDA inspectors, stayed at the same hotel in Incheon, from which Samsung Biologics arranged transportation to its facilities).

66. Approximately one month before the 2015 inspection, Marchesani and his team organized logistics including assembling documentation that may be requested by the FDA, assigning personnel to escort both inspectors during the audit and scribes to write down all communications with the inspectors in real time, and booking a large conference room for FDA and Samsung Biologics personnel and additional conference rooms for both of the clients.

67. Marchesani further recalled that during the 2015 inspection, both clients had personnel on site at Samsung Biologics. While Samsung Biologics handled all direct interactions with the FDA during the inspection, its clients had real-time access to all communications between

Samsung Biologics and the inspectors (except for communications relating exclusively to the other client) via software relaying the scribes' transcriptions. Samsung Biologics closely coordinated with its clients during the inspections, and worked with them to obtain information requested by the FDA during the inspection that was in the clients' possession. Marchesani and his team communicated with the clients and made sure that their input was incorporated into Samsung Biologics' responses to the FDA as appropriate. These were standard practices and the FDA was aware of such arrangements and the on-site presence of the client personnel.

68. At the conclusion of the 2015 inspection, the FDA informed Samsung Biologics that no quality issues were observed, and did not issue a Form 483. Samsung Biologics promptly discussed the outcome of the FDA inspection with its clients.

69. Marchesani does not recall any work relating to Checkpoint during his time at Samsung Biologics. Marchesani typically learned of new clients only once Samsung began manufacturing their products.

V. DEFENDANTS CONCEALED MATERIAL FACTS THAT CREATED RISKS TO FDA APPROVAL OF COSIBELIMAB

70. Throughout the Class Period, Defendants knew, but failed to disclose to investors, material information that created substantial risks for Checkpoint's business. Defendants failed to disclose that: (i) the FDA repeatedly issued Form 483s to Samsung Biologics with observations of numerous problematic conditions, including data integrity violations; (ii) the FDA's inspection of Samsung Biologics for Checkpoint's cosibelimab BLA observed critical data integrity issues, reported to Samsung Biologics in a Form 483 dated September 1, 2023; and (iii) by October 2, 2023 the FDA rejected Eli Lilly's BLA for lebrikizumab due to the same issues noted in the September 1, 2023 Form 483 to Samsung Biologics. These undisclosed facts severely undermined Defendants' misleading public statements during the Class Period that touted Checkpoint's

relationship with Samsung Biologics, presented cGMP violations by Checkpoint's CMO as mere hypothetical possibilities, and selectively disclosed only positive FDA communications concerning the cosibelimab BLA. Defendants' misrepresentations and omissions materially misled the investing public as to the prospects for near-term FDA approval of cosibelimab.

A. FDA Inspectors Observed cGMP Violations At Samsung Biologics Before And Throughout The Class Period, Including Data Integrity Violations

71. After each of the 11 FDA inspections of Samsung Biologics during 2016-2023, the FDA issued a Form 483 in which its inspectors noted significant cGMP violations.

72. The FDA's June 22, 2016 Form 483 contained 15 observations, including that "[t]he firm's monitoring program and equipment did not detect breaches in HEPA filters," and that "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed."

73. The FDA's July 25, 2017 Form 483 contained four observations, including that "[l]aboratory controls used to release [redacted] drug substance do not include scientifically sound and appropriate test procedures that assure conformance to appropriate standards of quality and purity," and that "[d]eviation investigations are inadequate."

74. The FDA's March 14, 2018 Form 483 contained two observations, namely that "QA oversight is in adequate [*sic*]" and that "[p]est control alert limit and action limit are inadequate."

75. The FDA's May 11, 2018 Form 483 contained five observations including that "[p]rocedures to prevent microbial contamination of drug products purporting to be sterile are not followed," and that "[t]he Quality Control Unit lacks authority to review production records to assure that no errors have occurred."

76. The FDA's June 26, 2018 Form 483 contained three observations including that "[e]mployees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions," and that "[e]quipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use."

77. The FDA's September 10, 2019 Form 483 contained three observations including that "[u]tilities and Equipment are not adequately maintained," and that "[w]ritten procedures to ensure control over the transfer of QC materials is inadequate."

78. The FDA's November 1, 2019 Form 483 contained one observation, that "[d]eviations from written production and process control procedures are not recorded and justified."

79. The FDA's August 24, 2021 Form 483 contained two observations, that "[a]cceptance criteria for cleaning validation are not always justified to prevent product cross-contamination," and that "[d]iscrepancies are not always investigated to identify the root cause to implement adequate corrective actions."

80. The FDA's June 9, 2022 Form 483 contained three observations, including that "[t]he endotoxin detection method is not reliable to detect endotoxin consistently in all the in-process and release samples for [redacted]," and "[w]ritten procedures for cleaning and maintenance provide inadequate description of actions to be taken and/or not followed."

81. The FDA's February 28, 2023 Form 483 contained three observations, including one relating to significant data integrity problems. Namely, that "[t]he responsibilities and procedures applicable to the quality control unit were not always fully followed," and more specifically that "deviations reported that the initial Quality Control Unit review of the referenced

records did not identify data discrepancy, data handling, and calculation errors and follow-up investigations were not complete." The Form 483 went on to cite as an example an instance of such a "data integrity violation" in which "during a data and audit trail review it was found that a single analyst reported that [redacted] was valid by intentionally deleting the specified [redacted] after [redacted] was completed."

82. Reporting by South Korean business news media outlet SBS Biz appears to provide additional details concerning the data integrity violation cited in the February 28, 2023 Form 483. In a June 1, 2023 article, adapted from a television broadcast, titled "Samsung Biologics Faces Controversy Over 'Manipulation of Data' . . . FDS 'Keeping a Close Watch'," (**Exhibit 6**) SBS Biz reported that "it has been confirmed through internal investigations that pharmaceutical data was intentionally altered." More specifically, "[s]ome employees within the Manufacturing Science and Technology (MSAT), one of the Samsung Biologics R&D research organizations produced invalid data during testing, which was then falsified to appear valid," and that "executives who were dismissed from their position were found to have deliberately engaged in this data falsification practice." The article further reported that "Samsung Biologics was found to have neglected the separation of software login credentials, a practice intended to prevent data tampering."

83. SBS Biz reported that Samsung Biologics' data tampering came to light when "a client, an overseas pharmaceutical company, flagged issues with the lab practice from the MSAT division of Samsung Bio during the second half last year. High executives of Samsung Bio visited the lab and found issues, which prompted a comprehensive internal investigation." According to the article, "[a]s a result, the head of the MSET [*sic*] division and other team leaders were relieved

of their positions." The article reported that South Korea's Ministry of Food and Drug Safety was "actively investigating the incident."

B. The FDA's August 2023 Inspection Of Samsung Biologics For The Cosibelimab BLA Observed Significant Data Integrity Problems

84. The FDA conducted a pre-announced inspection at Samsung Biologics from August 21 to September 1, 2023. The inspection covered multiple products, and served as the pre-approval inspection for Checkpoint's cosibelimab BLA, as well as the pre-approval inspection for Eli Lilly's lebrikizumab BLA. At the conclusion of the inspection, the FDA issued a Form 483 to Samsung Biologics containing six observations. *See* **Exhibit 4**.

85. The first observation on the Form 483 (observations are listed on Form 483 in order of risk significance, with the most significant risk first) stated that "[t]he Manufacturing Scientific Analytical Technology (MSAT) laboratory used in support of application submission testing data had inadequate controls over data integrity." More specifically, "[t]he MSAT laboratory was used in support of application submission data for [redacted] and [redacted] with the laboratory . . . having inadequate controls in assurance of data integrity since 2013," and "there is no means of determining with absolute certainty the true reliability of all test data."

86. The Form 483 further described Samsung Biologics' failure to correct known data integrity violations, apparently relating to some of the same issues reported by SBS Biz on June 1, 2023. According to the Form 483, following an initial internal audit of the MSAT Laboratory, "[a]t the request of Senior Quality Management, a subsequent audit was performed . . . with a critical observation pertaining to shared administration accounts and lack of data backup." In response, Samsung Biologics took insufficient corrective action "with improper implementation," and when a subsequent audit of the MSAT laboratory was conducted "observations found in 2021 [were] similarly found again." Even after this subsequent audit, Samsung Biologics' "remediation plan

did not fully assess data integrity gaps" and "no action [was] taken for shared administrative passwords."

87. Again echoing the recent reporting of SBS Biz, the Form 483 stated that Samsung Biologics "received observations and recommendations from a client audit 06 July 2022 and 01 September 2022 specific to the MSAT Laboratory data management practices, with Samsung senior executive tour of the MSAT Laboratory 14 September 2022 identifying sticky notes with system password written on PCs, use of shared administration account . . . uncontrolled spreadsheets used to track samples, [and] use of uncontrolled sheets to document test results," among other problems. The Form 483 noted that "similar findings were reported through the MSAT internal audits conducted" on two occasions. From "17 October 2022 to 16 January 2023" Samsung Biologics notified clients of "the MSAT laboratory deficiency . . . identified in September 2022."

88. The Form 483's data integrity observation concluded that Samsung Biologics "failed to address laboratory deficiencies in a timely manner in assurance of data quality, data integrity used in regulatory submissions."

89. Further details concerning the FDA's August 21 – September 1 inspection of Samsung Biologics are contained in the FDA's establishment inspection report summary. *See* **Exhibit 5**. According to the Endorsement (page 1 of 10) of inspection supervisor Richmond Yip dated October 12, 2023, the inspection's outcome was classified as "OAI," meaning Official Action Indicated, as relates to FDA product/assignment code 46832, which relates to pre-approval inspections. Following an inspection, the FDA assigns one of three classifications: no action indicated, which means no objectionable conditions or practices were found during the inspection; (ii) voluntary action indicated, which means objectionable conditions or practices were found, but

the agency is not prepared to take or recommend any administrative or regulatory action; or (iii) official action indicated, which means regulatory and/or administrative actions are recommended. An OAI classification indicates that the firm is not considered to be in an acceptable state of compliance with regards to CGMP and may be subject to regulatory or enforcement action, and such a classification may result in non-approval of pending applications. The Endorsement also reflects a "Withhold" recommendation, *i.e.* that approval for the regulatory applications at issue in the inspection should be withheld.

90. The OAI classification and withhold recommendation are further reflected in the EIR's list of Inspected Processes & District Decisions (page 3 of 10). This shows that, concerning FDA product/assignment codes 46832M relating to Pre-License Therapeutic Biological Product Inspections and 46832S relating to BLA Pre-License Inspections—Biosimilars, on October 5, 2023 inspector Jeffrey Raimondi classified the inspection as OAI with a "Withhold" recommendation, and similarly that on October 12, 2023 Richmond Yip classified the inspection as OAI with the remark "Witthold [*sic*] for MSAT data for PAI" (PAI refers to a Pre-Approval Inspection).

91. Reporting by SBS Biz revealed further details concerning the issues identified in the FDA's September 1, 2023 Form 483. In a November 6, 2023 article, adapted from a television broadcast, titled "Lilly in USA, 'There Are Data Management Issues at Samsung Bio' . . . Also Caught by FDA," (**Exhibit 7**) SBS Biz reported that the Samsung Biologics client whose audit discovered data integrity problems in 2022, as discussed in the Form 483, was Eli Lilly. The article states that "[a]ccording to internal sources, Lilly conducted two audits of the data management practices of Samsung Biologics' R&D organization, MSAT, on July 6 and September 1 of last year," and that "[f]ollowing Lilly's audit, senior executives at Samsung Biologics launched a

comprehensive investigation into data management in September of last year, leading to the resignation of a senior executive." SBS Biz further reported that "[t]he recent inspection appears to have taken place during the approval process for Lilly's atopic dermatitis treatment, 'Lebrikizumab'."

C. The FDA Rejected Eli Lilly's Lebrikizumab BLA By October 2023 Due To The Same cGMP Violations Identified In The August 2023 Inspection

92. In the third quarter of 2022 Eli Lilly submitted a BLA to the FDA for its atopic dermatitis treatment lebrikizumab. On October 2, 2023, Eli Lilly issued a press release announcing that the FDA had issued a complete response letter, rejecting its BLA. *See* **Exhibit 8**. According to the press release, the CRL "cited findings that arose during a multi-sponsor inspection of a third-party, contract manufacturing organization that included the monoclonal antibody drug substance for Lilly's lebrikizumab," and "[t]he letter stated no concerns about the clinical data package, safety or label for lebrikizumab."

93. Lebrikizumab is marketed under the name Ebglyss in the European Union. Product information for Ebglyss available from the European Medicines Agency lists the "manufacturer of the biological active substance" as Samsung Biologics.

94. Eli Lilly is one of the largest and most prominent company's in the pharmaceutical industry, and its announcement that the FDA had rejected its lebrikizumab BLA due to problems with its contract manufacturer was widely reported in industry publications. For example, on October 2, 2023 articles reporting this news were published online by Fierce Pharma, BioPharmaDive, FDA News, FirstWord Pharma, Managed Healthcare Executive, Dermatology Times, HCP Live, Medical Professionals Reference, and Pharmaphorum, among others, with additional reporting in the following days and weeks.

95. Defendants knew about Eli Lilly's announcement. Both Checkpoint and Eli Lilly were involved in the FDA's same pre-approval inspection of Samsung Biologics. Furthermore, the December 15, 2023 Checkpoint press release announcing the FDA's rejection of the cosibelimab BLA is evidently modeled after Eli Lilly's October 2, 2023 press release. Checkpoint's press release follows the same structure as Eli Lilly's, and repeats substantial portions of Eli Lilly's press release verbatim or with minor modifications. *See* **Exhibit 8** (providing copies of both press releases and a side-by-side comparison).

96. For example, among many other close similarities, Checkpoint's press release is titled "U.S. Food and Drug Administration Issues Complete Response Letter for Cosibelimab Solely Due to Inspection Findings at Third-Party Manufacturer," almost identically to Eli Lilly's, "U.S. Food and Drug Administration Issues Complete Response Letter for Lebrikizumab Based on Inspection Findings at Third-Party Manufacturer." Whereas Eli Lilly's press release stated that "[t]he letter stated no concerns about the clinical data package, safety or label" for lebrikizumab, Checkpoint's press release stated that "[t]he CRL did not sate any concerns about the clinical data package, safety, or labelling" for cosibelimab. The extraordinarily high degree of similarity in wording between the two press releases could not have occurred by mere coincidence.

VI. CHECKPOINT SOLD AT LEAST $79 MILLION OF ARTIFICIALLY INFLATED SECURITIES DURING THE CLASS PERIOD

97. Because Checkpoint had limited cash, no approved products, no sales, and minimal revenue during the Class Period, its survival depended on obtaining funds from investors. Checkpoint sold at least $79 million of securities during the Class Period. The following table shows Checkpoint's reported gross cash provided by financing activities (in thousands of dollars):

	2021 (excluding first quarter)	**2022**	**2023**	**TOTAL**
At-the-market offering	16,710	10,120	0	26,830
Registered direct offerings	0	7,500	33,621	41,121
Warrant exercise	0	0	11,134	11,134
TOTAL	16,710	17,620	44,755	79,085

98. In 2021 Checkpoint sold 11,899,983 million shares of common stock under its at-the-market offering for gross proceeds of $41.3 million, at an average selling price of $3.47 per share. At least $16.7 million of the gross proceeds were sold during the Class Period (which begins on March 10, 2021), as Checkpoint reported that during the first quarter of 2021 it sold 7,025,309 million shares for gross proceeds of $24.6 million, at an average selling price of $3.50 per share.

99. In 2022 Checkpoint sold 532,816 million shares of common stock under its at-the-market offering for gross proceeds of $10.1 million, at an average selling price of $18.99 per share. In December 2022 Checkpoint closed a registered direct offering for the sale of 950,000 shares and additional warrants, at a purchase price of $4.325 per share and associated warrants, raising gross proceeds of $7.5 million.

100. Effective December 6, 2022, Checkpoint conducted a 1-for-10 reverse stock split, whereby every 10 outstanding shares were converted into one share, in order to remain compliant with listing requirements of the Nasdaq Capital Market, which include a minimum bid price of at least $1 per share under NASDAQ Rule 5550(a)(2).

101. All of the financing raised by Checkpoint during 2023 took place during the Class Period, prior to its disclosure of the FDA's CRL in December 2023. In 2023 Checkpoint raised a total of $33.6 million in gross proceeds from four registered direct offerings. In February, April, May, and July of 2023 Checkpoint closed registered direct offerings of shares and warrants, at prices of $5.25 per share, $3.60 per share, $3.071 per share, and $3.09 per share.

102. On October 2, 2023, Checkpoint entered into an inducement agreement with a holder of existing Checkpoint warrants to exercise those warrants for 6,325,354 shares of common stock at a reduced exercise price of $1.76 per share, resulting in gross proceeds of $11.1 million to Checkpoint. Checkpoint had issued the warrants in December 2022 and February 2023 with exercise prices of $4.075 per share and $5.00 per share. As part of the inducement agreement Checkpoint agreed to issue new Series A and Series B warrants to the warrant holder, for the purchase of up to 6,325,354 shares per warrant series, at an exercise price of $1.51 per share.

103. All of Checkpoint's sales of its securities during the Class Period, totaling at least $79 million, were made at prices artificially inflated by Defendants' materially misleading statements and omissions.

VII. MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

104. During the Class Period, Defendants made multiple statements that misleadingly misrepresented and/or omitted to disclose that: (i) the FDA repeatedly issued Form 483s to Samsung Biologics with observations of numerous problematic conditions, including data integrity violations; (ii) the FDA's inspection of Samsung Biologics for Checkpoint's cosibelimab BLA observed critical data integrity issues, reported to Samsung Biologics in a Form 483 dated September 1, 2023; and (iii) by October 2, 2023 the FDA rejected Eli Lilly's BLA for lebrikizumab due to the same issues noted in the September 1, 2023 Form 483 to Samsung Biologics.

A. March 9, 2021 Press Release Regarding 2020 Results

105. The Class Period begins on March 10, 2021. On March 9, 2021, after the close of stock market trading, Checkpoint published a press release titled "Checkpoint Therapeutics Reports Full-Year 2020 Financial Results and Recent Corporate Highlights." Later that day, Checkpoint

filed a copy of the press release with the SEC as an exhibit to a Form 8-K signed by Defendant Oliviero.

106. The press release stated that "in November 2020, Checkpoint announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab."

107. The press release also quoted Defendant Oliviero stating "[w]e look forward to a transformative year as we continue our progress towards our first BLA submission with the U.S. Food and Drug Administration ('FDA') for cosibelimab in 2022."

108. The statements identified in ¶¶106-107 were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded, by March 9, 2021, the seven inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations, which created material risks to Defendants' planned BLA submission for cosibelimab.

B. March 12, 2021 Annual Report for 2020

109. On the morning of March 12, 2021 Checkpoint filed with the SEC its annual report for 2020 on Form 10-K. The annual report was signed by Defendant Oliviero, and included as an exhibit a Sarbanes-Oxley certification signed by Oliviero attesting to the accuracy and completeness of the information in the 10-K.

110. The 2020 annual report, under the headings "Business" and "Government And Industry Regulations," stated:

> As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP.

> Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. *If we, or our contract manufacturers, fail to comply*, then the FDA may not allow us to market products that have been affected by the failure.

111. The 2020 annual report, under the headings "Business" and "Supply and Manufacturing," stated:

> we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current GMP ("cGMP") regulations.
>
> * * *
>
> Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration ("DEA") and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations . . . We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. *If they are deemed out of compliance with cGMPs*, product recalls could result, inventory could be destroyed, production could be stopped, and supplies could be delayed or otherwise disrupted.

112. The 2020 annual report included a risk factor stating:

> The facilities used by our third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, but we do not control the day-to-day manufacturing operations of, and are dependent on, our third-party manufacturers for compliance with cGMP regulations for manufacture of our product candidates. *Third-party manufacturers may not be able to comply with the cGMP regulations* or similar regulatory requirements outside the United States.

113. The 2020 annual report included another risk factor stating:

> All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its establishment inspection program. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party suppliers and contract manufacturers, but we have little control over their compliance with these regulations.
>
> *Any failure to comply with applicable regulations may* result in fines and civil penalties, suspension of production, restrictions on imports and exports, suspension

> or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product and customer confidence in our product.

114. The statements identified in ¶¶110-113 were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded, by March 12, 2021, the seven inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations, and so compliance failures by Samsung Biologics were a presently existing fact, not merely a hypothetical possibility.

C. January 25, 2022 Cosibelimab Trial Results Conference Call

115. On January 25, 2022 Checkpoint held a conference call to announce certain Cosibelimab clinical trial results. After Defendant Oliviero presented the trial results a question and answer session followed.

116. H.C. Wainwright analyst Joseph Pantginis asked "[w]hat do you consider are the rate-limiting steps for the BLA? And I guess, any comments you could talk about with regard to CMC and any issues with regard to supply chain?"

117. Defendant Oliviero responded:

> Yeah. So any initial NDA or BLA for a company takes time to put together. We've been actually working on it for a number of months now for the sections we could put together, and with this data, we can now really hit the gas pedal on the additional sections. It does take time, and *we want to put in a quality filing to have our best shot at a first cycle approval. I think there's a very good probability that we will be successful there*, but we want to make sure it's right. So we've guided for a submission for later this year. There's no issues that we see that we can't overcome during the review, but until you go through it, you never know.
>
> As far as supply chain, *we're lucky to have the largest contract manufacturer in the world of biologics as our partner, that's Samsung Biologics as our contract manufacturer for drug substance and drug product.* They have incredible amounts of supply capacity there. Our current capacity allows us to get through initial launch, and then they still have additional capacity beyond that for us to continue to scale up for the potential increased sales, two, three, four, five years out from now, from initial launch. *So, we're very happy to have Samsung behind us and we're in good shape*.

118. The statements identified in the preceding paragraph were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded, by January 25, 2022, the eight inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations, which created material risks to FDA approval for Defendants' planned BLA submission for cosibelimab.

D. March 28, 2022 Annual Report for 2021

119. On the morning of March 28, 2022 Checkpoint filed with the SEC its annual report for 2021 on Form 10-K. The annual report was signed by Defendant Oliviero, and included as an exhibit a Sarbanes-Oxley certification signed by Oliviero attesting to the accuracy and completeness of the information in the 10-K.

120. The 2021 annual report repeated verbatim the text from Checkpoint's 2020 annual report quoted above at ¶¶110-113. Those statements as repeated in the 2021 annual report were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded, by March 28, 2022, the eight inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations, and so compliance failures by Samsung Biologics were a presently existing fact, not merely a hypothetical possibility.

E. August 12, 2022 Press Release Regarding Second Quarter 2022 Results

121. On the morning of August 12, 2022 Checkpoint published a press release titled "Checkpoint Therapeutics Reports Second Quarter 2022 Financial Results and Recent Corporate Highlights." Later that day, Checkpoint filed a copy of the press release with the SEC as an exhibit to a Form 8-K signed by Defendant Oliviero.

122. The press release stated:

> In July 2022, *Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls [CMC]* and clinical/non-clinical). Based upon favorable interactions with the agency, the planned BLA submission will include both the metastatic and locally advanced indications. Checkpoint also reached agreement with the FDA on all key aspects discussed with regard to the content of the upcoming BLA submission.

123. The press release quoted Defendant Oliviero as stating that "[o]ver the past few months, we have made substantial progress towards the regulatory submission for, and potential approval of, cosibelimab . . . Importantly, we successfully completed our pre-BLA meetings with the FDA in July, reaching agreement on all key aspects discussed with regard to the upcoming BLA submission."

124. The statements identified in ¶¶122-123 were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded, by August 12, 2022, the nine inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations, which created material risks to FDA approval for Defendants' planned BLA submission for cosibelimab.

F. January 18, 2023 Interview at B. Riley Oncology Conference

125. On January 18, 2023 Defendant Oliviero on behalf of Checkpoint participated in an interview as part of the B. Riley Securities' 3rd Annual Oncology Conference, with B. Riley analyst Mayank Mamtani. The interview was live streamed and later made available for replay online.

126. Mamtani asked about the cosibelimab BLA process:

> And then maybe just to go back on the thesis to the regulatory filing, that's maybe something you'd have to work through as you get through the approval process. Could you maybe also touch on the non-clinical components like CMC or having another sort of larger study in place? Could you maybe touch on what some of those components would look like as you go through the review process?

127. Defendant Oliviero responded in part:

> This was again conducted to study under an IND so *we had FDA buy-in since the beginning* of the clinical development program and that's buy-in not just for the cutaneous squamous cell carcinoma study, you know, the design, the size the endpoints, but also *on the CMC program. We have the largest contract manufacturer in the world of biologics behind us manufacturing this, that's Samsung Biologics, and so having the FDA involved from the beginning, seeing the batches that we've run and the that assays we've developed, and taking their input and applying it to our program, is extremely important and I think a wise decision on our part, so that we have a complete package and essentially what the FDA's expecting of us going into submitting that BLA earlier this month*.

128. The statements identified in the preceding paragraph were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by January 18, 2023, the nine inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; and by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory. These adverse facts created material risks to FDA approval for Defendants' BLA submission for cosibelimab.

G. March 30, 2023 Press Release Regarding 2022 Results

129. On March 30, 2023, after the close of stock market trading, Checkpoint published a press release titled "Checkpoint Therapeutics Reports Full-Year 2022 Financial Results and Recent Corporate Highlights." The next morning, Checkpoint filed a copy of the press release with the SEC as an exhibit to a Form 8-K signed by Defendant Oliviero.

130. The press release stated:

> In July 2022, *Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls* and clinical/non-clinical). Based upon favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cSCC indications. Checkpoint also reached agreement with the FDA on all key aspects discussed regarding the content of the BLA submission.

131. The press release quoted Defendant Oliviero as stating that "we began 2023 with the submission of our Biologics License Application ('BLA') to the U.S. Food and Drug

Administration ('FDA') seeking approval of cosibelimab . . . Our BLA submission was subsequently accepted for filing and is under active review with a Prescription Drug User Fee Act ('PDUFA') goal date of January 3, 2024."

132. The press release further stated that "[i]n its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned."

133. The statements identified in ¶¶130-132 were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by March 30, 2023, the ten inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; and the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data. These adverse facts created material risks to FDA approval for Defendants' BLA submission for cosibelimab.

H. March 31, 2023 Annual Report for 2022

134. On March 31, 2023, after the close of stock market trading, Checkpoint filed with the SEC its annual report for 2022 on Form 10-K. The annual report was signed by Defendant Oliviero, and included as an exhibit a Sarbanes-Oxley certification signed by Oliviero attesting to the accuracy and completeness of the information in the 10-K.

135. The 2022 annual report repeated verbatim the text from Checkpoint's 2021 and 2020 annual reports quoted above at ¶¶110-113. Those statements as repeated in the 2022 annual report were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by March 31, 2023, the ten inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant

cGMP violations; by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; and the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data. As such, compliance failures by Samsung Biologics were a presently existing fact, not merely a hypothetical possibility.

I. September 11, 2023 Presentation At H.C. Wainwright Investment Conference

136. On September 11, 2023 Defendant Oliviero on behalf of Checkpoint gave a presentation as part of the H.C. Wainwright 25th Annual Global Investment Conference, The presentation was live streamed and later made available for replay online.

137. Oliviero stated concerning the cosibelimab BLA:

> So, with regard to the regulatory timeline, with regard to our BLA, again, we submitted in January, it was accepted for filing in March. That's when we learned that there was no advisory committee meeting planned by the FDA. We were assigned that PDUFA goal date of January of 2024. Most recently, we announced that *we completed our mid-cycle communication meeting with the FDA, whereby the FDA communicated no significant review issues and no safety concerns identified to date, so doing very well towards our approval*. The late-cycle meeting is now scheduled for late October, and we look forward to moving through the rest of the process and having a successful PDUFA goal date in January.

138. The statements identified in the preceding paragraph were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by September 11, 2023, the 11 inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data, which had led to an internal investigation at Samsung Biologics and its firing of multiple executives; and during August 21-September 1,

2023 the FDA conducted a pre-approval inspection of Samsung Biologics for the cosibelimab BLA which resulted in a Form 483 noting serious, long-standing, and unremedied data integrity problems that undermined the reliability of application submission data. These adverse facts created material risks to FDA approval for Defendants' BLA submission for cosibelimab.

J. September 28, 2023 Presentation At Cantor Global Healthcare Conference

139. On September 28, 2023 Defendant Oliviero on behalf of Checkpoint participated in an interview as part of the Cantor Global Healthcare Conference, with Cantor analyst Jennifer Kim. The interview was live streamed and later made available for replay online.

140. Kim asked about the cosibelimab BLA, "the PDUFA date [is] coming up in just a couple of months. Maybe recap the kinds of discussions you've had with the FDA and communications and what steps are left between now and that date?".

141. Oliviero responded:

> Sure. So it was a very typical process for a full BLA review. We filed or submitted the BLA back in January of this year 2023. It was accepted for filing, which is when we found out that the FDA was not planning an advisory committee meeting. We then progressed through the review. Again a very typical review. Most recently, *we had our mid-cycle meeting with the FDA, whereby they conveyed to us that there were no significant issues, no safety concerns thus far with the BLA review, so very clean bill of health as of that point in time with the FDA. And now we've entered into the labeling discussion, part of the BLA process, so it's moving forward very nicely*, and we're looking forward to hearing the results very soon.

142. The statements identified in the preceding paragraph were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by September 28, 2023, the 11 inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data, which had led to an internal investigation

at Samsung Biologics and its firing of multiple executives; and during August 21-September 1, 2023 the FDA conducted a pre-approval inspection of Samsung Biologics for the cosibelimab BLA which resulted in a Form 483 noting serious, long-standing, and unremedied data integrity problems that undermined the reliability of application submission data. These adverse facts created material risks to FDA approval for Defendants' BLA submission for cosibelimab.

K. November 13, 2023 Quarterly Report For The Third Quarter Of 2023

143. On November 13, 2023, after the close of stock market trading, Checkpoint filed with the SEC its quarterly report for the third quarter of 2023 on Form 10-Q. The quarterly report was signed by Defendant Oliviero and included as an exhibit a Sarbanes-Oxley certification signed by Oliviero attesting to the accuracy and completeness of the information in the 10-Q.

144. The quarterly report stated that:

> *Our contract manufacturer for cosibelimab has received certain observations from the FDA on Form 483* related to a recent multi-sponsor on-site inspection. While *we believe the manufacturer will adequately respond to and address the observations during our BLA review timeline*, there is no guarantee that the FDA will agree with the response and remediations in a timely manner or at all, which could negatively impact our ability to obtain regulatory approval for cosibelimab or obtain approval within projected timelines.

145. The statements identified in the preceding paragraph were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by November 13, 2023, the 11 inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; by January 16, 2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data, which had led to an internal investigation at Samsung Biologics and its firing of multiple executives; the Form 483 referred to in Defendants' statement noted serious, long-standing, and unremedied data integrity problems that undermined

the reliability of application submission data; two FDA inspectors had already classified the recent Samsung Biologics inspection as Official Action Indicated and recommended withholding approval for cosibelimab due to the MSAT data integrity problems; and the FDA had already rejected Eli Lilly's lebrikizumab BLA due to the same issues noted in the Form 483 referred to in Defendants' statement. These adverse facts were essential to an accurate understanding of the significance of the Form 483, and severely undermined Defendants' purported belief that Samsung Biologics would adequately address the issues in the Form 483 within the cosibelimab BLA review timeline.

L. November 13, 2023 Press Release Regarding Third Quarter 2023 Results

146. Also on November 13, 2023, after the close of stock market trading, Checkpoint published a press release titled "Checkpoint Therapeutics Reports Third Quarter 2023 Financial Results and Recent Corporate Highlights." Later that day, Checkpoint filed a copy of the press release with the SEC as an exhibit to a Form 8-K signed by Defendant Oliviero.

147. The press release stated that "[i]n March 2023, Checkpoint announced the FDA accepted the BLA filing for cosibelimab and set a Prescription Drug User Fee Act ('PDUFA') goal date of January 3, 2024. The FDA has indicated that an advisory committee meeting to discuss the application is not planned."

148. The press release quoted Defendant Oliviero as stating "[t]he January 3, 2024, action date for our Biologics License Application ('BLA') for cosibelimab is fast-approaching, and we continue to work closely with the U.S. Food and Drug Administration ('FDA') in completing their review."

149. The statements identified in ¶¶147-148 were materially false and/or misleading, and/or failed to disclose material adverse facts because, as Defendants knew or recklessly disregarded: by November 13, 2023, the 11 inspections of Samsung Biologics conducted by the FDA since 2016 each resulted in a Form 483 noting significant cGMP violations; by January 16,

2023 Samsung Biologics had notified its clients of severe data integrity problems in its MSAT laboratory; the FDA's February 28, 2023 Form 483 to Samsung Biologics reported significant data integrity problems including intentional deletion of data, which had led to an internal investigation at Samsung Biologics and its firing of multiple executives; during August 21-September 1, 2023 the FDA conducted a pre-approval inspection of Samsung Biologics for the cosibelimab BLA which resulted in a Form 483 noting serious, long-standing, and unremedied data integrity problems that undermined the reliability of application submission data; two FDA inspectors had already classified the recent Samsung Biologics inspection as Official Action Indicated and recommended withholding approval for cosibelimab due to the MSAT data integrity problems; and the FDA had already rejected Eli Lilly's lebrikizumab BLA due to the same issues noted in the September 1, 2023 Form 483. These adverse facts created material risks to FDA approval for Defendants' BLA submission for cosibelimab.

VIII. THE FDA REJECTED THE COSIBELIMAB BLA, CAUSING A DRAMATIC DECLINE IN CHECKPOINT'S STOCK PRICE

150. On December 18, 2023, the material risks and adverse information previously concealed by Defendants' false and misleading statements and omissions materialized when Checkpoint revealed that the FDA had issued a complete response letter for the cosibelimab BLA, rejecting the application. As a result, Checkpoint's stock price suffered steep losses.

151. On the morning of December 18, 2023 Checkpoint published a press release titled "U.S. Food and Drug Administration Issues Complete Response Letter for Cosibelimab Solely Due to Inspection Findings at Third-Party Manufacturer." The press release stated "[t]he CRL only cites findings that arose during a multi-sponsor inspection of Checkpoint's third-party contract manufacturing organization as approvability issues to address in a resubmission," and that "[t]he

CRL did not state any concerns about the clinical data package, safety, or labeling for the approvability of cosibelimab."

152. The press release quoted Defendant Oliviero stating "[a]s the only deficiencies relate to the FDA's inspection of our third-party contract manufacturing organization, we believe we can address the feedback in a resubmission to enable marketing approval in 2024," and that "[w]e are committed to working closely with our third-party manufacturer and the FDA on our resubmission." Checkpoint also filed a copy of the press release with the SEC as an exhibit to a Form 8-K signed by Defendant Oliviero.

153. On this news, Checkpoint's share price fell $1.49 as compared to the prior day closing price, or 44.9%, to close at $1.83 per share on December 18, 2023, on extremely heavy trading volume.

154. Independent observers noted the obvious connection between the dramatic decline in Checkpoint's stock price and the news of the CRL. In a December 19, 2023 article titled "FDA rejects Checkpoint's skin cancer candidate over issue at contract manufacturer," industry publication Fierce Pharma reported that "with the CRL, Checkpoint's share price plummeted on Monday from $3.27 to $1.54," and that "[t]he CRL puts Checkpoint in a precarious spot. In its third-quarter earnings presentation, the company reported cash and equivalents of just $1.8 million."

IX. AFTER THE CLASS PERIOD, DEFENDANTS REVEALED ADDITIONAL DETAILS ABOUT EVENTS LEADING TO THE FDA'S REJECTION

155. On January 18, 2024 Defendant Oliviero on behalf of Checkpoint participated in an interview as part of the B. Riley Securities' 4th Annual Oncology Conference, with B. Riley analyst Mayank Mamtani.

156. Mamtani asked about the FDA's complete response letter for the cosibelimab BLA:

> Could you share the nuances of what the issues were? It seems more CDMO directed where it could have been related to not just your filing but also other products that may have been going through the same QC facility. So when you meet with the FDA in your Type A would you get any insight on how that correspondence is going between the FDA and CDMO? Because it seems like a little detached from what you could control with your filing, for example?

157. Defendant Oliviero replied:

> So first off, the specifics around it, it was around not the actual manufacturing itself but around the lab that tests the product associated with certain CMC studies that we've done. This lab, and more specifically the quality oversight of the lab by the CMO. And yes, it does affect other people as well. It's a general oversight issue and I would expect it's something they can resolve with the FDA. Now as you mentioned the back and forth is between the FDA and this contract manufacturer though they share everything with us, they redact any other names and this and that, but they share it all with us and the FDA doesn't really go directly to us. However, we do have this opportunity at this planned Type A FDA meeting that we will have after this Complete Response Letter to have a very frank conversation with the FDA and if things aren't resolved by that point, hopefully get much more specific with them about what's left, you know, tell us what's left so we can really push them hard, get it done, and get this resubmission in as quickly as possible.

158. On May 20, 2024 Defendant Oliviero on behalf of Checkpoint participated in an interview as part of the H.C. Wainwright 2nd Annual BioConnect Investor Conference, with H.C. Wainwright analyst Joseph Pantginis. Responding to questions from an audience member, Defendant Oliviero stated about Checkpoint's contract manufacturer, "[t]he issues related to their quality oversight of lab testing in one of their labs. It affected not just us but other clients."

X. ADDITIONAL SCIENTER ALLEGATIONS

159. As alleged herein, Defendants acted with scienter because Defendants: knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

160. As set forth elsewhere herein in detail, Defendant Oliviero, by virtue of his receipt of information reflecting the true facts regarding Checkpoint, his control over, and/or receipt and/or modification of Checkpoint's allegedly materially misleading misstatements and/or his association with the Company which made him privy to confidential proprietary information concerning Checkpoint, participated in the fraud alleged herein.

A. Defendants' Own Statements Show They Knew Of The FDA's September 1, 2023 Form 483 To Samsung Biologics

161. As Defendants stated in Checkpoint's November 13, 2023 Form 10-Q, "[o]ur contract manufacturer for cosibelimab has received certain observations from the FDA on Form 483 related to a recent multi-sponsor on-site inspection," showing their knowledge of the Form 483, while still concealing its observations of significant data integrity violations.

162. Defendant Oliviero's attempt to hedge his misleading statement in response to an analyst's question during Checkpoint's September 28, 2023 presentation at the Cantor Global Healthcare Conference further shows his knowledge of adverse information from the FDA. At that point, the FDA had concluded its pre-approval inspection of Samsung Biologics and issued its Form 483 observing significant data integrity violations four weeks earlier. When Cantor analyst Jennifer Kim asked Oliviero to "recap the kinds of discussions you've had with the FDA," Oliviero responded "[m]ost recently, we had our mid-cycle meeting with the FDA, whereby they conveyed to us that there were no significant issues, no safety concerns thus far with the BLA review, so very clean bill of health *as of that point in time* with the FDA." Checkpoint's mid-cycle meeting occurred some time before August 14, 2023, when the Company first announced that its "mid-cycle communication meeting with the FDA was successfully completed." If Oliviero was not aware of adverse developments post-dating the mid-cycle meeting, such as the September 1, 2023 Form 483, there would have been no reason for his caveat, "as of that point in time."

B. Defendants Selectively Disclosed Only Positive FDA Communications About The Cosibelimab BLA While Concealing Negative Information

163. As detailed above, Defendants repeatedly touted to investors every positive interaction they had with the FDA regarding the cosibelimab BLA. *See* ¶¶122-23, 127, 130-31, 137, 141, 147-48. In stark contrast, Defendants concealed adverse information such as the significant data integrity violations observed in the FDA's September 1, 2023 Form 483.

164. Defendants have also concealed what the FDA told Checkpoint in its late-cycle meeting for the cosibelimab BLA. Under the standard BLA processing timeline, the late-cycle meeting is to take place approximately nine months after submission. As Defendant Oliviero stated at the September 11, 2023 H.C. Wainwright 25th Annual Global Investment Conference, Checkpoint's late-cycle meeting with the FDA was then scheduled for "late October." Despite touting the results of all other BLA processing milestones, Defendants have never publicly discussed what happened at the late-cycle meeting.

165. According to the FDA's Desk Reference Guide for New Drug Application and Biologics License Application Reviews, 20 days before the late-cycle meeting the FDA sends the applicant an "Agency Background Package" in preparation for the late-cycle meeting, which is to include a brief memorandum from the review team outlining any outstanding substantive application issues. The late-cycle meeting is intended to share information, identify deficiencies, and plan the rest of the review. Potential topics for discussion at the late-cycle meeting include major deficiencies identified to date and any available information on the status of inspections.

166. By late October 2023, the FDA had issued its September 1 Form 483 noting significant data integrity violations, and two FDA inspectors had already classified the inspection of Samsung Biologics as OAI and recommended withholding approval, with one specifically noting that the withhold recommendation was due to the issues concerning "MSAT data" observed

at the pre-approval inspection. These are the same issues that ultimately led to the FDA rejecting the BLA. Therefore, it is highly likely that these issues were discussed in Checkpoint's late October late-cycle meeting with the FDA. Defendants' decision to conceal from investors what was discussed at the late-cycle meeting is further evidence of their scienter.

C. Defendant Oliviero Held Himself Out As Knowledgeable About Samsung Biologics And The Cosibelimab BLA

167. As alleged herein, Defendant Oliviero repeatedly held himself out as knowledgeable regarding all aspects of Checkpoint's business, including Checkpoint's relationship with Samsung Biologics, and interactions with the FDA concerning the cosibelimab BLA.

168. On August 11, 2021, industry news website BioSpace.com published an interview with Defendant Oliviero under the title "Get to Know James Oliviero, CEO and President of Checkpoint Therapeutics." In response to the question "[w]hat are your daily activities as CEO and president?" Oliviero replied:

> We're a small company so my role is very much hands-on. That's part of my personality as well. I like to have my finger on the pulse of the different aspects of the company. I would say half the job of a CEO in a publicly traded biotechnology company is on the investor outreach and relations front, presenting the company to the investment community. And then the other half of the time is managing your development programs and overseeing the company. I am heavily involved in working with my team to design our clinical trials and manage the clinical research organizations that we outsource to.

169. As detailed above, Defendant Oliviero repeatedly discussed matters relating to the cosibelimab BLA and Checkpoint's interactions with the FDA concerning the BLA. *See* ¶¶117, 123, 127, 131, 137, 141, 148, 152. As stated in the FDA's EIR summary, from June 12, 2023 to June 16, 2023, the FDA inspected Checkpoint's headquarters in Waltham, Massachusetts. Defendant Oliviero was not present on the day when the inspectors arrived, but personally attended the remaining four days of the inspection. The EIR summary indicates that all correspondence to Checkpoint from the FDA should be sent by mail to Defendant Oliviero's attention, and to his

Company email address.

170. As detailed above, Defendant Oliviero repeatedly discussed matters relating to Checkpoint's relationship with Samsung Biologics. *See* ¶¶117, 127, 152, 157-58. Defendant Oliviero also signed Checkpoint's Master Services Agreement with Samsung Biologics, and was personally involved in announcing Checkpoint's Product Specific Agreement with Samsung Biologics concerning cosibelimab (Checkpoint never publicly disclosed the PSA so it is not known whether Oliviero also signed that agreement).

D. Defendant Oliviero Had Financial Motives To Conceal Risks To Cosibelimab's Approval

171. Defendant Oliviero's incentive compensation and insider stock sales provided motives to artificially inflate Checkpoint's stock price.

172. Defendant Oliviero made several substantial sales of Checkpoint stock throughout the Class Period, which were out of line with his prior trading activity. From Oliviero's initially reporting his beneficial ownership of Checkpoint stock in 2016 up until the beginning of the Class Period, his only sales of Checkpoint stock had been made to satisfy withholding tax obligations in connection with the vesting of incentive compensation. Oliviero disclaimed having any discretion with respect to such withholding tax-related sales.

173. The following table summarizes the information reported by Defendant Oliviero concerning his Class Period sales of Checkpoint stock that were not made to satisfy withholding tax obligations:

Date	Shares Sold	Price Per Share	Sale Proceeds	Shares Owned After Sale (including shares subject to vesting)
4/4/2022	86,353	$1.79	$154,571.87	2,873,291
4/5/2022	14,030	$1.77	$24,833.10	2,859,261
4/13/2022	21,258	$1.51	$32,099.58	2,838,003
6/17/2022	228,000	$1.09	$248,520.00	2,610,003
6/21/2022	21,000	$1.09	$22,890.00	1,589,003
6/22/2022	12,000	$1.09	$13,080.00	2,577,003
6/23/2022	15,000	$1.11	$16,650.00	2,562,003
TOTAL	397,641		$512,644.55	

At the times of the above reflected sales, Oliviero was not able to sell the full number of shares shown as owned by him, because many such shares remained subject to delayed vesting schedules.

174. Defendant Oliviero did not report any purchases of Checkpoint stock during the Class Period. All of his Checkpoint stock was obtained as compensation.

175. In addition to making outright sales of Checkpoint stock, Defendant Oliviero also transferred substantial amounts of Checkpoint stock to an irrevocable trust for the benefit of his minor children. Oliviero's public SEC filings concerning such transfers state that he "is not a trustee of the trust and has no investment control over the securities held by the trust."

Date	Shares Transferred	Closing Price on Date	Value of Transfer	Shares Owned After Transfer (including shares subject to vesting)
9/26/2022	600,000	$0.98	$589,800.00	1,961,990
2/24/2023	42,000	$4.35	$182,700.00	381,580
8/16/2023	12,510	$1.51	$18,890.10	381,580
TOTAL	654,510		$791,390.10	

At the times of the above reflected transfers, Oliviero was not able to transfer the full number of shares shown as owned by him, because many such shares remained subject to delayed vesting schedules. The number and price of the 600,000 shares transferred in September 2022 is before giving effect to Checkpoint's December 2022 1-for-10 reverse stock split (equivalent to 60,000

shares with a closing price per share of $9.83 on a post-split basis). The numbers and prices of the 2023 transfers are after giving effect to the reverse stock split.

176. After making such transfers to his children's trust, Oliviero ceased reporting the stock as beneficially owned by him, and so did not publicly disclose when or if any such stock was sold by the trust. However, it is highly likely that the trust promptly sold most or all of such Checkpoint stock. Laws applicable to trustees generally require them to act as a prudent investor and to diversify the trust's assets. For example, the widely adopted Uniform Prudent Investor Act states that "[a] trustee shall invest and manage trust assets as a prudent investor would" and that "[a] trustee shall diversify the investments of the trust unless the trustee reasonably determines that, because of special circumstances, the purposes of the trust are better served without diversifying." It would be highly imprudent, and contrary to trust diversification requirements, to invest any substantial portion of a trust's assets in the stock of a small biopharmaceutical company with no sales and no approved products, like Checkpoint.

177. In addition to providing the *de facto* ability to sell Checkpoint stock without public disclosure of any sales, transferring stock to his children's trust provided another benefit to Defendant Oliviero. Transferring assets to a trust for which the transferor is not the trustee and retains no investment authority may make it substantially more difficult, or even impossible, for the transferor's judgment creditors to access those assets.

178. Checkpoint's compensation scheme also gave Defendant Oliviero financial motives to conceal adverse information and artificially inflate Checkpoint's stock price.

179. Defendant Oliviero's total compensation from Checkpoint during the Class Period was as follows:

	2021	2022	2023
Salary	540,000	594,000	635,580
Stock Awards	1,417,570	1,151,150	720,000
Non-Equity Incentive Plan	334,800	297,000	286,011
TOTAL	2,292,370	2,042,150	1,641,591

180. During the Class Period, Defendant Oliviero's employment agreement with Checkpoint has provided for accelerated vesting of a substantial number of otherwise restricted shares upon Checkpoint reaching certain market capitalization thresholds. Upon Checkpoint reaching a market capitalization of $500 million, 111,111 shares (before taking into account the December 2022 1-for-10 reverse split) of Oliviero's restricted stock would become vested. Similarly, upon Checkpoint reaching a market capitalization of $750 million, an additional 111,111 shares (before taking into account the December 2022 1-for-10 reverse split) of Oliviero's restricted stock would become vested.

181. The stock based compensation for Defendant Oliviero was issued under Checkpoint's Amended and Restated 2015 Incentive Plan. While Defendants did not disclose the specific performance-based criteria used to determine such awards during the Class Period, the plan provides that performance goals may include metrics such as "Stock price or performance," "Total shareholder return," "Market capitalization," and "Corporate financing activities."

XI. LOSS CAUSATION

182. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

183. During the Class Period, Plaintiffs and the Class purchased Checkpoint Securities at artificially inflated prices. The price of Checkpoint common stock significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

XII. CLASS ACTION ALLEGATIONS

184. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities who purchased the publicly traded common stock of Checkpoint, and/or purchased publicly traded call options on such stock, and/or wrote publicly traded put options on such stock, between March 10, 2021 and December 15, 2023, both dates inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, Fortress Biotech, Inc., any entity in which Defendants have or had a controlling interest, and any trust of which Defendant Oliviero is the settler or which is for the benefit of Defendant Oliviero and/or member(s) of his immediate family.

185. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Checkpoint's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds or thousands of members in the proposed Class. Millions of Checkpoint shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Checkpoint or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

186. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

187. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

188. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Checkpoint; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

189. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XIII. UNDISCLOSED ADVERSE FACTS

190. The market for Checkpoint's shares was open, well-developed and efficient at all relevant times. As a result of Defendants' materially false and/or misleading statements, and/or failures to disclose, Checkpoint's shares traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased Checkpoint's shares relying upon the integrity of the market price of the Company's shares and market information relating to Checkpoint and have been damaged thereby.

191. During the Class Period, Defendants materially misled the investing public thereby inflating the price of Checkpoint's shares, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading for the reasons set forth herein and because they failed to disclose material adverse information and/or misrepresented the truth about Checkpoint's business, operations, and prospects as alleged herein.

192. At all relevant times, the material misrepresentations and omissions and undisclosed scheme particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Checkpoint's prospects and engaged in a scheme to do the same. These material misstatements and/or omissions and/or conduct had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its prospects, thus causing the Company's shares to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements and/or conduct during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's shares at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

XIV. APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

193. The market for Checkpoint's shares was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Checkpoint's shares traded at artificially inflated prices during the Class Period. Plaintiffs

and other members of the Class purchased the Company's shares relying upon the integrity of the market price of Checkpoint's shares and market information relating to Checkpoint, and have been damaged thereby.

194. During the Class Period, the artificial inflation of Checkpoint's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Checkpoint's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Checkpoint and its business, operations, and prospects, thus causing the price of the Company's shares to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's shares at such artificially inflated prices, and each of them has been damaged as a result.

195. At all relevant times, the market for Checkpoint's shares was an efficient market for the following reasons, among others:

(a) Checkpoint shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Checkpoint filed periodic public reports with the SEC and/or the NASDAQ;

(c) Checkpoint regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on

the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the press; and

(d) Checkpoint was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms.

196. As a result of the foregoing, the market for Checkpoint's shares promptly digested current information regarding Checkpoint from all publicly available sources and reflected such information in Checkpoint's share price. Under these circumstances, all purchasers of Checkpoint's shares during the Class Period suffered similar injury through their purchase of Checkpoint's shares at artificially inflated prices and a presumption of reliance applies.

197. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material omissions set forth above, that requirement is satisfied here.

XV. NO SAFE HARBOR

198. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be

characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Checkpoint who knew that the statement was false when made.

XVI. FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

199. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

200. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (iii) cause Plaintiffs and other members of the Class to purchase Checkpoint's shares at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

201. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares in an effort to maintain

artificially high market prices for Checkpoint's shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) — (c). All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

202. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Checkpoint's financial well-being and prospects, as specified herein.

203. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Checkpoint's value, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Checkpoint and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares during the Class Period.

204. Defendant Oliviero's primary liability and controlling person liability arise from the following facts: (i) Defendant Oliviero was a high-level executive at the Company during the Class Period and a member of the Company's management team; (ii) Defendant Oliviero, by virtue of his responsibilities and activities as an officer of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) Defendant Oliviero enjoyed significant personal contact and familiarity with the Company's management team and was advised of, and had access to, internal reports and other

data and information about the Company's operations at all relevant times; and (iv) Defendant Oliviero was aware of the Company's dissemination of information to the investing public which he knew and/or recklessly disregarded was materially false and misleading.

205. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Checkpoint's prospects from the investing public and supporting the artificially inflated price of its shares. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

206. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Checkpoint's shares was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's shares were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the shares trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Checkpoint's shares during the Class Period at artificially high prices and were damaged thereby.

207. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were unaware of their falsity and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding Checkpoint, which was not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased their Checkpoint shares, or, if they had acquired such shares during the Class Period, they would not have done so at the artificially inflated prices which they paid.

208. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

209. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's shares during the Class Period.

XVII. SECOND CLAIM

Violation of Section 20(a) of The Exchange Act
Against Defendant Oliviero

210. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

211. Defendant Oliviero acted as a controlling person of Checkpoint within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions and his ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false statements disseminated to the investing public, Defendant Oliviero had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. Defendant Oliviero was provided with or had unlimited access to copies of the Company's reports, press releases, public

filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

212. In particular, Defendant Oliviero had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular decisions giving rise to the securities violations as alleged herein, and exercised the same.

213. As set forth above, Checkpoint and Defendant Oliviero each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendant Oliviero is liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's shares during the Class Period.

XVIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XIX. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

DATED: August 23, 2024

GLANCY PRONGAY & MURRAY LLP

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Lead Counsel for Lead Plaintiff Hamilton Bailey and Named Plaintiff Reiko Juhst

PROOF OF SERVICE

I, the undersigned say:

I am not a party to the above case and am over eighteen years old.

On August 23, 2024, I served true and correct copies of the foregoing document, by posting the document electronically to the ECF website of the United States District Court for the Southern District of New York, for receipt electronically by the parties listed on the Court's Service List.

I affirm under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on August 23, 2024.

s/ Garth Spencer
Garth Spencer